IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Selis
Application No.: 10/631,204
Filed: 07/31/2003
For: BIOPSY DEVICES AND METHODS

Attorney Docket No.: 1142-001
Group No.: 3773
Examiner: Tyson, Melanie Ruano

Commissioner for Patents
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1. I am a radiologist employed by Southfield Radiology Associates as a Doctor. I have been involved in performing biopsies, and I have been involved with performing mammograms and breast biopsies for more than ten years. I have been regularly and continuously performing such procedures since well prior to 2004. Attached as Exhibit A is my Curriculum Vitae.

2. I work with Dr. James E. Selis at Southfield Radiology Associates, where we are business "partners."

3. I have reviewed published U.S. Patent Application No. 2004/0097981 ("the Application"), attached as Exhibit B, which I understand belongs to Dr. James E. Selis. I do not own rights in the Application.

4. I have reviewed U.S. Patents Nos. 6,766,186 by Hoyns et al., attached as Exhibit C, and 6,425,903 by Voegele, attached as Exhibit D.

5. Based on my experience I am familiar numerous breast tissue markers existing prior to May 2004.

6. In my work as a radiologist it has been my experience that one difficulty which faces breast tissue markers has been migration of the breast tissue markers away from the area intended to be marked. This problem is described in Exhibits F-M. This problem is also recognized in the Hoyns patent. Specifically, it states at col. 1, lines 36-39 that "[i]mplants placed loose within the tissues have a tendency to migrate, and this tendency is particularly acute in the case of fatty tissue, such as the breast."

7. Migration of tissue markers can pose difficulties in further diagnosing and treating disorders. For instance, without precise location of the tissue marker some lesions can be hard to localize and monitor during subsequent radiographic examinations.

8. I am also aware of what I believe to be a relatively recent entry into the commercial market of a product that appears to have virtually the identical wire structure of U.S. Patent Application No. 2004/0097981 and the clips of Figures 1, 3, 7, 8, 11C, 13A, 13B, 15, 16G, 16I, and 16J. I have purchased and used that clip and it has a comparable structure to the structure explained in the Application. That clip when deployed generally has the following shape:

 .

9. The Selis Application of Exhibit B depicts a marker that generally has the shape of :

 .

10. My observation has been that this shape and the shape of the commercial marker of Exhibit E is verbally described by the following paragraph:

An improved clip for marking breast tissue of a biopsy site or the site of an aspirated cyst during a radiographic analysis, the clip extending along an axis between a first end and a second end and comprising a metal structure consisting essentially of:

a first arc segment having a first end located at the first end of the clip and a second end located at the second end of the clip;

a second arc segment having a first end located at the first end of the clip and a second end located at the second end of the clip, the second arc segment being coplanar with the first arc segment; and

an apex disposed along the clip axis defining where the first and second arc segments adjoin and converge,

wherein, after being driven through an exit opening of a delivery tube of a delivery device, the metal structure penetrates breast tissue, wherein the metal structure is configured so that

(i) it resides entirely within the delivery tube prior to being driven through the exit opening,

(ii) it deploys through a hole of the delivery device, and

(iii) in both an original pre-deployment state and a post-deployment state:

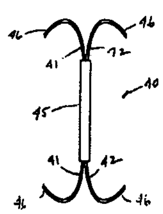
the first ends of the first and second arc segments project in a direction outward relative to the clip axis opposite to that of the second ends of the first and second arc segments,

the first ends of the first and second arc segments project in a direction generally away from the second ends of the first and second arc segments;

(iv) while it resides within the delivery tube prior to being driven through the exit opening the arc segments are arcuate; and

(v) the first ends and the second ends of the first and second arc segments penetrate breast tissue after being driven through the exit opening of the delivery tube, and thereby substantially prevent migration of the deployed clip within the breast.

11. In reviewing the patents in Exhibit C and D, I have observed at least the following differences between the above-mentioned  clip of the Selis Application (which is depicted to the left and in Figs. 1, 3, 7, 8, 11C, 13A, 13B, 15, 16G, 16I, and 16J of the Selis Application generally as two back-to-back C-shaped segments)and both of these references. According to Hoyns there is shown a marker having the following shape:



My understanding of Hoyns is that because of wrap around of the "barbs" 46 and because of winding Hoyns requires and relies upon elasticity shape memory action for self-closing and self-clamping and specifically points its barbed ends toward each other on each side after deployment.

a. The various teachings of the Hoyns reference indicate to me that the Hoyns clip requires a large amount of stored energy to self-close or self-clamp. This is exemplified by the following passage from Hoyns, found in column 6, lines 48-50 where Hoyns states, "As a marker 40 exits the forward end of the cannula 30, the barbs 46 spring outward, as shown in FIG. 17, piercing the target tissue 34 and anchoring the marker to the tissue." One foreseeable issue with the Hoyns clip comes during deployment. The Hoyns clip relies on the springing action to anchor; therefore, the Hoyns clip must contact tissue upon deployment. If the Hoyns clip is placed in a biopsy cavity, and does not immediately contact tissue, the arms will spring back and it is likely no tissue will be pierced. Without piercing tissue the Hoyns clip will not be anchored and will be prone to migrate.

b. It is my belief that when clips having geometry of arms similar to the Hoyns clip (e.g. they wrap around and have barb ends 46 that point to each other) are deployed there is a large amount of residual energy in the wires. The energy causes the ends to rapidly assume their final configuration. As a result of the clip changing configuration to its final state the Hoyns clip would not give me confidence in predictability that the clip would stay located at the biopsy site without migrating.

c. The Hoyns reference does not suggest modification by cutting off the barb ends of the clip to arrive at a structure like that of Dr. Selis. Hoyns specifically teaches clamping upon itself, thus requiring a large springing action, and self-closing or self-clamping (clamping between opposing barbs). The Hoyns reference teaches away from the design shown in the Selis Application because the Selis Application does not use any of the clamping taught by Hoyns, to prevent migration. In fact, Hoyns requires the springing action to prevent migration, which would not work and would not get a predictable spring to achieve a clamp if modified as shown in the Selis Application.

d. In looking at the Hoyns patent I cannot limit myself to a finite body of predictable modifications to achieve resistance to migration that would necessarily include the structure of the Selis Application. By looking at the Hoyns clip I can envision a virtually endless number of variations that might be pursued to improve migration resistance. None of these would necessarily involve adopting the geometry of the Sellis Application. For example modifications might have included adopting an A-symmetrical geometry, using dissimilar materials for the barbs, varying the material properties along the device, varying the dimensions of the device, varying orientation of the barbs in three-dimensional space, and so on and so forth. Looking at Hoyns and the specified objective to provide clamping; I simply do not see, in the absence of any hind sight and without using the Selis Application to get there, how a person skilled in the art prior to the Selis Application would have arrived at the Selis structure.

e. By way of example, looking at Figures 15 -17, the arms will wrap around and try to grab tissue. If an arm does not hit tissue and attach the clip can migrate. If only one barb hits tissue or one arm hits tissue first it is possible that, due to the amount of stored energy, the clip is susceptible to torquing or spiraling and could spring itself into a different area.

12. I also interpret that Hoyns does not describe exiting through a side hole of a tube especially along a ramp. It strikes me that the Hoyns design would not be practical for that type of exit because the pressure of the barbs against the sidewall of the tube would prevent

the Hoyns clip from traveling up the ramp and out the side of the tube because the barbs would likely catch the base of the ramp and prevent the clip from traveling up the ramp and out of the tube. Also the Hoyns design is described to have its "barbs" totally straightened while in a delivery device. This degree of deformation of the "barbs" appears to be critical to both achieve the necessary springing for clamping and be able to fit in the tube as desired.

13. In summary, the conventional wisdom has been that there needs to be a springing that brings about a clamping. The Hoyns reference reinforces this notion by teaching and describing all of the markers as springing outward and clamping.

14. The clip of Dr. Selis' design fixes the problems of the current designs by: (1) easily marking a biopsy site for future reference, (2) having markers that are useful for radiographic imaging detection, (3) having a means of easily deploying the markers and even having markers that are deployable through a biopsy device, and (4) having clips that prevent migration. These are all described in the Selis Application, such as in paragraphs 040, 041, 059, and 077. The Dr. Selis solution surprisingly achieves these results without the need for high amounts of springing, without clamping, or both. Dr. Selis has done so contrary to conventional wisdom. These features likewise are performed by the commercial clip that I have described in Paragraph 8. The success I have experienced by using the commercial clip, offered by a competitor, has confirmed this for me.

15. The scope of this Affidavit is only for the purpose of comparing the Application to the two references cited by the USPTO and the clip of Exhibit E. By giving this Affidavit, I make no comment or representation about the standard of care in my profession nor does this Affidavit make any representation about the performance of any clip of the Selis Applications or the commercial clip referenced herein, or that any such clip is appropriate for all applications.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the Application or any patent issued thereon.

Dr. Thomas Hall

Dated: 12/9/2008